ANDA 75-404

June 4, 1999

Danbury Pharmacal, Inc.
Attention: Ann Mullarkey
131 West Street
Danbury, CT 06810

Dear Madam:

This is in reference to your abbreviated new drug application dated June 25, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Famotidine Tablets USP, 10 mg (OTC).

Reference is also made to your amendments dated August 27, and October 16, 1998; and March 23, April 12, and April 21, 1999.

We have completed the review of this abbreviated application and have concluded that, based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted labeling. Therefore, the application is **tentatively approved**. This determination is based upon information available to the Agency at this time, (i.e., information in your application and the status of current good manufacturing practices (CGMPs) of the facilities used in the manufacture and testing of the drug product), and is subject to change on the basis of new information that may come to our attention. This letter does not address notice issues related to the 180-day exclusivity provisions under Section 505(j)(5)(B)(iv) of the Act.

The listed drug product (RLD) referenced in your application, Pepcid AC Tablets of Merck Research Laboratories, is subject to periods of patent protection which expire on October 15, 2000 (U.S. patent 4,283,408, the ‘408 patent), May 2, 2015 (U.S. patent 5,667,794, the ‘794 patent), and December 29, 2015 (U.S. patent 5,854,267, the ‘267 patent). Your application contains a Paragraph IV Certification to both the ‘794 and ‘267 patents under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of this drug product will not infringe on either of the patents, or that the patents are invalid or

unenforceable. Section 505(j)(5)(B)(iii) of the Act provides that approval shall be made effective immediately unless an action is brought for infringement of either patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(I) is received by the patent holder and the holder of the new drug application (NDA) for the RLD. You have notified the Agency that Danbury Pharmacal, Inc. (Danbury) has complied with the requirements of Section 505(j)(2)(B) of the Act and that no action for infringement against either the '794 or '267 patents was brought against Danbury within the statutory forty-five day period. In addition, your application contains a Paragraph III Certification to U.S. patent 4,283,408 (the '408 patent) under Section 505(j)(2)(A)(vii)(III) of the Act. Therefore, final approval of your application may not be made effective pursuant to 21 U.S.C. 355(j)(5)(B)(ii) of the Act until the '408 patent has expired, i.e., currently October 15, 2000.

Because the Agency is granting a tentative approval for this application, please submit an amendment at least 60-days (but not more than 90-days) prior to the date you believe your application will be eligible for final approval. This amendment should identify changes, if any, in the conditions under which the product was tentatively approved, and should include updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. An amendment should be submitted even if none of these changes were made. This submission should be designated clearly in your cover letter as a MINOR AMENDMENT. In addition to this amendment, the Agency may request at any time prior to the date of final approval that you submit an additional amendment containing the information described above.

Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your application, or may result in a delay in the issuance of the final approval letter.

Any significant changes in the conditions outlined in this abbreviated application, as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (CGMPs) are subject to Agency review before final approval of the application will be made.

The drug product that is the subject of this abbreviated application may not be marketed without final Agency approval under Section 505 of the Act. The introduction or delivery for

introduction into interstate commerce of this drug product before the final approval date is prohibited under Section 501 of the Act and 21 U.S.C. 331(d). Also, until the Agency issues the final approval letter, your drug product will not be deemed approved for marketing under 21 U.S.C. 355, and will not be listed in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list, (the “Orange Book”) published by the Agency. Should you believe that there are grounds for issuing the final approval letter prior to the expiration of the ‘408 patent on October 15, 2000, you should amend your application accordingly.

At the time you submit any amendments, please contact Mark Anderson, Project Manager, at (301) 827–5849, for further instructions.

Sincerely yours,

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research